achieving the applicant's goals and objectives will be evaluated, and how, once the plan has been completed, its impact on environmental health and human exposure issues in the applicant's community will be assessed.

6. Staffing, Management System, and Facilities (5 Percent)

The extent to which the applicant describes the staff available or anticipated to conduct the planning activities and how they will be managed. The applicant must describe the organizational setting and facilities available to support the development of the plan, to accumulate and analyze data and other information related to planning. Applicants should also describe planning to provide IRB review when biomonitoring programs are implemented and discuss the impact of the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) on their plan.

7. Budget (Not Scored)

The extent to which the applicant provides a detailed budget and narrative justification consistent with stated objectives and planned program activities.

H. Other Requirements

Provide CDC with the original plus two copies of:

1. Annual progress reports, no more than 30 days after the end of the report period;
2. Financial status report, no more than 90 days after the end of the budget period;
3. Final financial report and performance report, no more than 90 days after the end of the project period; and
4. Completed planning document, no later than the end of the third quarter of year two.

Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I in the application kit.

AR–7 Executive Order 12372 Review
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2010
AR–12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301 and 317 of the Public Health Service Act, 42 U.S.C. sections 241 and 247b, as amended. The catalog of Federal Domestic Assistance number is 93.283.

J. Where To Obtain Additional Information

This and other CDC announcements can be found on the CDC home page Internet address—http://www.cdc.gov Click on ''Funding'' then ''Grants and Cooperative Agreements.''

To receive additional written information and to request an application kit, call 1–888–GRANTS4 (1–888–472–6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Sonia V. Rowell, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, (MS E–13), Atlanta, GA 30341–4146, Telephone: (770) 488–2724, E-mail address: svp1@cdc.gov.

For program technical assistance contact: Dayton T. Miller, Ph.D., National Center for Environmental Health, Centers for Disease Control and Prevention, 4770 Buford Highway, NE (MS F–18), Atlanta, GA 30341–3724, Telephone: (770) 488–4452, E-mail address: dtm1@cdc.gov.

Dated: April 30, 2001.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–11215 Filed 5–3–01; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

CDC Advisory Committee on HIV and STD Prevention: Meeting

In accordance with section l0(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: CDC Advisory Committee on HIV and STD Prevention.

Times and Dates: 8:30 a.m.–5 p.m., June 4, 2001. Place: Holiday Inn, 130 Clairmont Ave, Decatur, Georgia 30030.

Place: 8:30 a.m.–5 p.m., June 5, 2001. Corporate Square Office Park, Corporate Square Boulevard, Building 8, 1st Floor Conference Room, Atlanta, Georgia 30329.

Status: Open to the public, limited only by the space available. The meeting room will accommodate approximately 100 people.

Purpose: This Committee is charged with advising the Director, CDC, regarding objectives, strategies, and priorities for HIV and STD prevention efforts including maintaining surveillance of HIV infection, AIDS, and STDs, the epidemiologic and laboratory study of HIV/AIDS and STDs, information/education and risk reduction activities designed to prevent the spread of HIV and STDs, and other preventive measures that become available.

Matters to be Discussed: Agenda items include issues pertaining to (1) HIV prevention-care interface (2) HRSA–CDC linkages in terms of preventing STDs other than HIV (3) Syphilis elimination. Agenda items are subject to change as priorities dictate.

For Further Information Contact: Paulette Ford, Committee Management Analyst, National Center for HIV, STD, and TB Prevention, 1600 Clifton Road, NE, Mailstop E–07, Atlanta, Georgia 30333. Telephone 404/639–8008, fax 404/639–3125, e-mail pbf7@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: April 30, 2001.

John Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 01–11218 Filed 5–3–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0185]

Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Postmarketing Expedited Safety Reports; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the

availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Postmarketing Expedited Safety Reports.'' This is one in a series of guidance documents on providing regulatory submissions to FDA in electronic format. This specific guidance discusses issues related to the electronic submission of postmarketing expedited safety reports for drug products marketed for human use with new drug applications (NDAs) and abbreviated new drug applications (ANDAs), prescription drug products marketed for human use without an approved NDA or ANDA, and therapeutic biological products marketed for human use with biologic license applications (BLAs). This guidance does not apply to vaccines. The submission of these reports in an electronic format will significantly improve the agency's efficiency in processing, archiving, and reviewing the reports.

DATES: Submit written comments on the draft guidance by July 3, 2001. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Deborah Yaplee, Center for Drug Evaluation and Research (HFD–400), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3237, aersesub@cder.fda.gov; or

Michael Fauntleroy, Center for Biologics Evaluation and Research (HFM–588), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–5101, Fauntleroy@cber.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Description of the Guidance

FDA is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Postmarketing Expedited Safety Reports.'' FDA has cooperated with industry associations and the regulatory authorities of certain other nations to promote international harmonization of regulatory requirements. Much of this effort has been coordinated through the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). Under the auspices of the ICH, standards for electronic submission of safety information for human drug and biological products have been developed, including a standard medical terminology for regulatory purposes, ICH M1; electronic standards for the transfer of regulatory information, ICH M2; and standardized data elements for transmission of individual case safety reports, ICH E2B and E2BM formats.

This draft guidance is intended to provide guidance to industry regarding submission of postmarketing expedited safety reports to FDA electronically using the standards established by the ICH. FDA believes the changes recommended by the ICH will result in more effective and efficient safety reporting to regulatory authorities worldwide.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The draft guidance represents the agency's current thinking on providing postmarketing expedited safety reports in an electronic format. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Paperwork Reduction Act of 1995

This notice contains no new collections of information. The information requested for marketed human drug and biological products is already covered by the collection of information on postmarketing safety reporting regulations (21 CFR 310.305, 314.80, and 600.80) submitted to the Office of Management and Budget (OMB) for review and clearance. This notice merely provides applicants with an alternative mechanism for submitting postmarketing expedited safety reports to the agency.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), OMB approved the information collection for MedWatch—The FDA Medical Products Reporting Program (Forms FDA 3500 and FDA 3500A) and assigned it OMB control number 0910–0291. The approval for 0910–0291 expires on April 30, 2003.

OMB also approved the information collection for adverse experience reporting for marketed drugs and licensed biological products and assigned them OMB control numbers 0910–0230 and 0910–0308, respectively. The approval for 0910–0230 expires on May 31, 2002, and the approval for 0910–0308 expires on April 30, 2003.

IV. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cder/guidance/index.htm or at http://www.fda.gov/cber/guidelines.htm.

Dated: April 27, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–11235 Filed 5–3–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for the opportunity for public comment on proposed data collection projects [Section 3506 (c) (2) (A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13], the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To